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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,649	07/30/2003	Nigel Robert Arnold Beeley	18528.636 / 0212-CIP-9	6846

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,649	BEELEY ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005 and 05 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,12-16,22-26,32-36,42-46,52-56,62-66 and 72-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *74,80,86,92,98,104 and 110* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20050406*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

1. Applicant's election with traverse of the generic sequence SEQ ID NO:21, and the specific sequence SEQ ID NO:9, in the reply filed on May 5, 2005 is acknowledged. The traversal is on the ground(s) that there is no burden to the examiner because the species would have already been searched before issuing the first action on the merits. This is not found persuasive because unclaimed species, especially of the number now recited in instant claims 77, 83, 89, 95, 101, 107, and 113, are generally not searched until they are actually claimed.

The requirement is still deemed proper and is therefore made FINAL.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 76, 78, 82, 84, 88, 90, 94, 96, 100, 102, 106, 108, and 112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a method of treating a subject suffering from PCOS using a peptide compound which is "capable of binding to or activating a GLP-1 receptor in vivo". The use of the word "or" in the quoted phrase implies that the claims embrace the use of peptide compounds which are capable of binding to but not necessarily activating GLP-1, e.g., embrace the use of GLP-1 antagonists. However, there is no original disclosure of the use of GLP-1 antagonists to treat subjects suffering from PCOS. Rather, the original disclosure appears

to be limited to the use of GLP-1 agonists. See, e.g., page 2, line 26 - page 3, line 26. Applicants have not indicated where the original disclosure supports the new claim limitations.

4. Claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 76, 78, 82, 84, 88, 90, 94, 96, 100, 102, 106, 108, and 112 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of peptide compounds which are capable of binding to and activating a GLP-1 receptor in vivo, i.e. GLP-1 agonists, does not reasonably provide enablement for the use of GLP-1 antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of the invention is the use of peptide compounds, including GLP-1 antagonists, to treat subjects having PCOS. With respect to (2), the prior art does not disclose the use of GLP-1 antagonists to treat subjects having PCOS. With respect to (3), the relative skill in the art is high. With respect to (4), the pharmaceutical arts is relatively unpredictable. With respect to (5), as noted above, the claims embrace the administration of peptide compounds which are capable of binding to a GLP-1 receptor in vivo but which do not necessarily activate the receptor, i.e. which

are GLP-1 antagonists. With respect to (6) and (7), the direction and guidance disclosed by Applicants, and the experiments which are provided, are limited to the use of GLP-1 agonists. Applicants provide no theory of operation or actual experimental results by which peptide compounds having opposite activities can all be used to treat subjects with PCOS. With respect to (8), the quantity of experimentation necessary to in order to be able to treat subjects with PCOS using compounds having the opposite activity as the disclosed GLP-1 agonists would be vast. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 73, 75-79, 81-85, 87-91, 93-97, 99-103, 105-109, and 111-113 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/317,126. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '126 application anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 73, 75-79, 81-85, 87-91, 93-97, 99-103, 105-109, and 111-113 are directed to an invention not patentably distinct from claims 1-18 of commonly assigned U.S. patent application 10/317,126. Specifically, see the above provisional obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. patent application 10/317,126, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

7. Instant claims 1-3, 5, 6, 12, 13, 15, 16, 22, 23, 25, 26, 32, 33, 35, 36, 42, 43, 45, 46, 52, 53, 55, 56, 62, 63, 65, 66, 72, 73, 75, 78, 79, 81, 84, 85, 87, 90, 91, 93, 96, 97, 99, 102, 103, 105, 108, 109, and 111 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date

of parent application 10/317,126 because the parent application, under the test of 35 U.S.C. 112, first paragraph, because the parent application discloses the claimed invention.

Instant claims 4, 14, 24, 34, 44, 54, 64, 74, 76, 77, 80, 82, 83, 86, 88, 89, 92, 94, 95, 98, 100, 101, 104, 106, 107, 110, 112, and 113 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 10/317,126 because the parent application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the administration of exendin peptides and analogs in general (note that the disclosure at page 13, line 9 - page 14, line 12, of the parent application is limited to three specific exendins); does not disclose the use of exendin-4 acid (compare page 13, lines 19 and 28); and does not disclose all of the exendin analogs having SEQ ID NOS:20-27. Disclosure of a few species does not provide support for the more generic claim terminology or for the other patentably distinct species currently claimed.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 4, 14, 24, 34, 44, 54, 64, 76, 77, 82, 83, 88, 89, 94, 95, 100, 101, 106, 107, 112, and 113 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2004/0029784. The U.S. Patent Application Publication '784 was published based upon U.S. patent application 10/317,126, which forms the basis of the provisional obviousness-type double patenting rejection set forth above. Claims 1-18 of the U.S. Patent Application Publication '784 clearly anticipate the instant claims. Note that exendin-4 corresponds to Applicants' elected species of SEQ ID NO:9. In addition, U.S. Patent Application Publication '784 at column 4, Table 1, teaches exendin 4 (9-39 NH_2) to be a useful exendin analog.

10. Claims 4, 14, 76, 77, 82, and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by Knudsen (U.S. Patent Application Publication 2004/0180824). Knudsen teaches and claims treating polycystic ovarian syndrome by administering a combination of an exendin-4 compound and a thiazolidinedione insulin sensitizer. The exendin-4 compound can be exendin-4 (which corresponds to Applicants' elected species SEQ ID NO:9) or insulinotropic fragments of exendin-4. The sensitizer can be troglitazone, rosiglitazone, or pioglitazone. The subject to be treated can be a human. Administration can be subcutaneous or by means of an infusion pump, and can be either sequential or concurrent. See, e.g., paragraph [0027], [0041], and [0076], and claims 1, 2, 5, 16, 19, and 29.

Knudsen is available as prior art under 35 U.S.C. 102(e) against the instant claims because the subject matter disclosed in Knudsen and relied upon in the rejection is also disclosed in Knudsen's priority document, provisional application 60/431,999. The subject matter disclosed in Knudsen and relied upon in the rejection is entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/431,999 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the subject matter. See, e.g., page 89, lines 23-34; page 13, lines 23-25; and claims 1, 2, 6, 13, 16, and 24 of the provisional application. This provisional application can be viewed at, and/or a copy ordered from, Public PAIR at http://portal.uspto.gov/external/portal/pair.

11. Applicant's arguments filed February 7, 2005 and May 5, 2005 have been fully considered but they are not persuasive.

The requirement to show common ownership with copending application serial number 10/317,126 at the time this invention was made is maintained. Applicants have argued that the

requirement can only be made where the copending application is prior art to the instant claims, and have provided a partial statement for those claims pending in the instant application which are not entitled to the filing date of parent application 10/317,216. However, this requirement is based upon the copending application being available as prior art under 35 U.S.C. 102(f) and/or (g). The relative filing dates of this and the copending application are irrelevant to rejections involving patents and/or applications potentially available as prior art under 35 U.S.C. 102(f) and/or (g). The requirement to show common ownership is set forth in MPEP 804, Charts I-B and/or III-B, and has arisen because different inventive entities are claiming obvious variations of the same invention.

The anticipation rejection based upon U.S. Patent Application Publication 2004/0029784 is maintained to the extent that Applicants' claims are not entitled to the benefit of the filing date of parent application 10/317,126 and to the extent that the U.S. Patent Application Publication '784 teaches the claimed subject matter. The U.S. Patent Application Publication '784 teaches the same exendin peptides used for treating the same subjects suffering from PCOS, and thus is deemed to clearly anticipate the instant claims.

The anticipation rejection based upon Knudsen (U.S. Patent Application Publication 2004/0180824) is maintained to the extent that Applicants' claims are not entitled to the benefit of the filing date of parent application 10/317,126, to the extent that subject matter relied upon in Knudesn is disclosed in its provisional application, and to the extent that Knudesn teaches the claimed subject matter. [Note that to the extent that Knudesn et al might teach exendin-4 in its unamidated, i.e. acid, form in paragraph [027], this disclosure is not found in Knudsen's

provisional application, and therefore claims 74 and 80 are not included in the listing of rejected claims.]

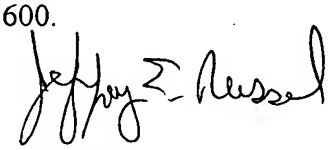
12. Claims 74, 80, 86, 92, 98, 104, and 110 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

May 27, 2005

Continuation of Disposition of Claims: Claims rejected are 1-6,12-16,22-26,32-36,42-46,52-56,62-66,72,73,75-79,81-85,87-91,93-97,99-103,105-109 and 111-113.